REMARKS

This paper is filed in response to the Office Action dated December 12, 2008. Claims 1, 4, 7, 8, and 26-31 are pending in the Application, and claims 7 and 8 are withdrawn from consideration. Claims 1, 4, and 26-31 stand rejected. It is requested that amendments to claim 1 and that new claim 47 be entered in the Application. It is respectfully submitted that the amendments add no new matter to the Application; support for the amendments can be found, for example, in paragraphs [0051], [0137], and [0138] and in Figs. 8A-8F. Reconsideration of the Application in view of the amendments and the following remarks is respectfully requested.

Claim Rejections – 35 U.S.C. § 103

Claims 1 and 28-31 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 6,485,513, which issued to Fan ("Fan") in view of U.S. Patent No. 6,063,114, which issued to Nash et al. ("Nash"); claims 4 and 26 stand rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fan and Nash in view of U.S. Patent No. 6,482,227, which issued to Solovay ("Solovay"); and claim 27 stands rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Fan and Nash in view of U.S. Patent No. 6,428,550, which issued to Vargas et al. ("Vargas"). The Applicants respectfully traverse these rejections. However, in order to expedite prosecution of the Application, independent claim 1 has been amended.

Claim 1

The Applicants respectfully submit that amended claim 1 is not obvious in view of Fan and Nash, whether these references are considered individually or in combination. For example, amended claim 1 recites, *inter alia* (emphasis added):

> inserting, after removal of the introducer from the vein, the second end of the graft vessel into the sheath such that at least a portion of the stent is within the vein, ***wherein the vein has an inner diameter equal to or smaller than the outer diameter of the stent***; and
>
> removing the sheath from the vein such that the second end of the graft vessel is anastomosed to the vein via the stent ***to yield an end-to-end anastomosis***.

The Application clearly distinguishes between end-to-end anastomoses and end-to-side anastomoses. For example, as described in paragraph [0045] of the specification, "[a]n anastomosis is termed end-to-end when the terminal portions of tubular structures are anastomosed, and it is termed end-to-side when the terminal portion of a tubular structure is anastomosed to a lateral portion of another tubular or hollow structure." Additionally, Fig. 8F of the Application (reproduced below) provides an example of an end-to-end anastomosis formed in a manner on which the method of claim 1 would read. In the illustrated example, a graft vessel 50 includes a stented end 60 that comprises a stent 360. The stented end 60 is positioned within the lumen of a vein 40 so as to be substantially coaxial therewith and is attached to the vein 40 in an end-to-end anastomosis via the stent 360. *See also* Present Application, paragraphs [0046] and [0051].

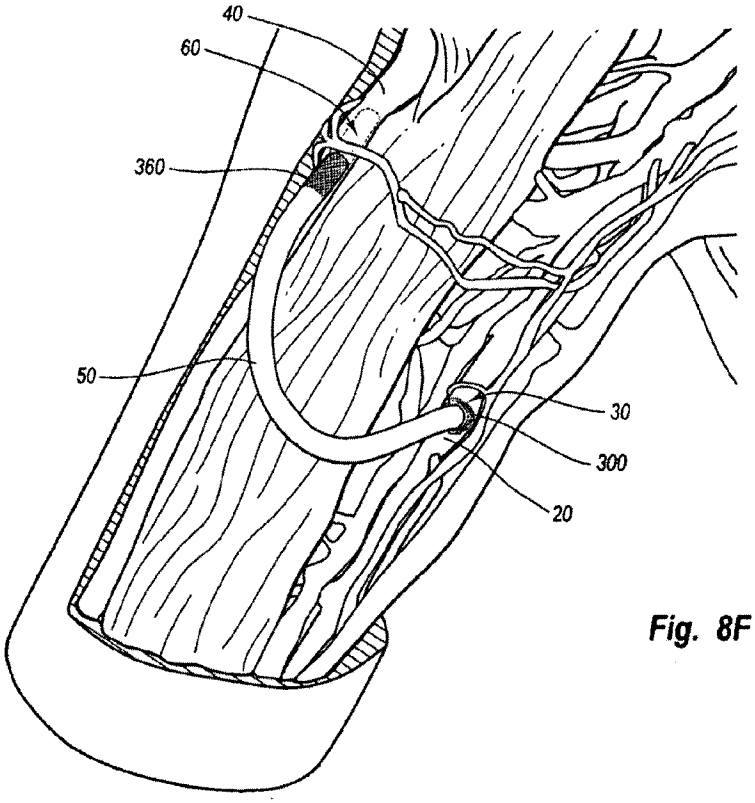

Fig. 8F

Fig. 8F of the Present Application

As discussed in paragraph [0137], "the stented end of the graft vessel device may be folded, rolled, or otherwise compressed into" a sheath. "In this manner, the stented end may be inserted into a . . . vein having an equal or smaller diameter than that of the stented end of the graft vessel." As discussed in paragraph [0138], after the sheath is "removed, the [end-to-end] anastomosis procedure is complete." It is clear from at least the foregoing portions of the disclosure that it is an outer diameter of the

stented end when in an uncompressed state that is compared with the size of an inner diameter of the vein.

In contrast to the method recited in claim 1, both Fan and Nash disclose methods for creating end-to-side anastomoses. In particular, Fan emphasizes the desirability of forming a "true" or "pure" end-to-side anastomosis, in contrast to prior art devices that "partially obstruct a vessel or divert flow in an irregular or inappropriate manner." Fan, col. 1, lines 45-54 and 62-63; col. 2, lines 14-18; col. 3, lines 24-37. As shown, for example, in FIG. 4 (reproduced below), the graft vessels 10, 10' each have an outer diameter smaller than an inner diameter of a natural vessel 20 to which they are attached in an end-to-side anastomosis. As described in Fan,

> the method of the present invention proceeds by inserting graft 10 through an opening in the side wall of a natural vessel 20 (FIG. 4) to form a true end-to-side anastomosis therewith. As shown in FIG. 4, when installed in this fashion, the anchor hooks 9 and membrane 9a reside inside of the vessel 20 and bear against the inner wall 20a of the vessel, thus preventing dislodgement of the graft 10 from the vessel. FIG. 4 further shows a second graft 10' in a perspective view from outside the vessel. As shown, the grafts 10, 10' join the vessel at substantially normal incidence. Further, as seen in the partial cut away view, within the vessel the graft ending lies closely against and fastens tangent to the endoluminal surface of the vessel wall without projecting into the blood flow lumen 21.

Id. at col. 3, lines 24-37.

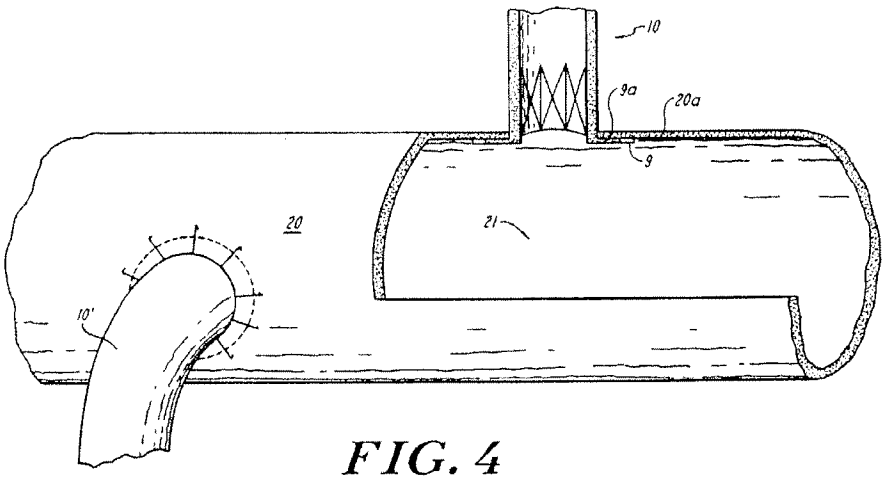

FIG. 4

FIG. 4 of Fan

In view of the foregoing, it is respectfully submitted that modifying the disclosure of Fan to achieve an end-to-end anastomosis such as that recited in claim 1 would impermissibly render Fan unsatisfactory for its intended purpose (i.e., the creation of a "true" end-to-side anastomosis"). *See* M.P.E.P. § 2143.01 (V). Such a modification also would impermissibly change the principle of operation of this reference. *See id.* at § 2143.01 (VI). Moreover, such modifications would not be obvious in view of Nash, since this reference likewise discloses an end-to-side anastomosis arrangement. *See, e.g.*, Nash, FIGS. 2, 7, 8, 10, 12, 13, and 14; col. 6, lines 42-59; col. 9, lines 18-26; col. 10, lines 47-67; and col. 11, lines 1-6.

For at least the foregoing reasons, the Applicants respectfully request that the rejection of claim 1 under 35 U.S.C. § 103(a) be removed.

Claims 4 and 26-31

Each of claims 4 and 26-31 depends from independent claim 1 and thus includes all of the limitations of this claim. Therefore, for at least the reasons discussed above with respect to claim 1, the Applicants respectfully submit that none of the references Fan, Nash, Solovay, and Vargas, whether considered individually or in combination, render obvious any of claims 4 and 26-31. The Applicants thus respectfully request that the rejection of these claims under 35 U.S.C. § 103(a) be withdrawn.

New Claim 47

Newly added claim 47 depends from independent claim 1, and thus includes all of the limitations of this claim. Therefore, for at least the reasons discussed with respect to claim 1, the Applicants respectfully submit that claim 47 is patentable and thus request favorable consideration of this claim.

Rejoinder

The Applicants respectfully submit that amended independent claim 1 is generic to at least withdrawn claims 7 and 8. Further, as discussed above, the Applicants respectfully submit that claim 1 is allowable. Therefore, the Applicants hereby request rejoinder of claims 7 and 8 because each of these claims depends from an allowable independent claim and requires all the limitations of the independent claim from which it depends. *See* M.P.E.P. § 821.04.

Conclusion

In view of the foregoing, it is believed that all of the pending claims are patentable in their present form and thus a Notice of Allowance for this case is respectfully requested. The Applicants respectfully note that it is the combination of features recited in a claim that renders the claim patentable, and not any feature or features of the claim in isolation. Accordingly, the Applicants respectfully submit that none of the references discussed above, whether considered individually or in combination, renders obvious:

> [a] method for connecting a vessel to another vessel comprising:
>
> providing a synthetic graft vessel having a first end and a second end, the second end coupled with a stent such that portions of the stent are fixedly attached to the second end of the graft vessel, wherein the stent defines an outer diameter;
>
> anastomosing the first end of the graft vessel to a side of an artery to yield an end-to-side anastomosis;
>
> inserting an introducer into a vein;
>
> inserting a sheath into the vein such that, when both the introducer and the sheath are in the vein, at least a portion of the introducer is within the sheath;
>
> removing the introducer from the vein;
>
> inserting, after removal of the introducer from the vein, the second end of the graft vessel into the sheath such that at least a portion of the stent is within the vein, wherein the vein has an inner diameter equal to or smaller than the outer diameter of the stent; and

> removing the sheath from the vein such that the second end of the graft vessel is anastomosed to the vein via the stent to yield an end-to-end anastomosis, wherein a first end of the stent is within the vein and a second end of the stent is outside the vein,

as recited in independent claim 1. Likewise, none of the methods recited in dependent claims 4, 7, 8, 26-31 are obvious in view of the cited references.

The Examiner is invited to contact the undersigned attorney should any impediment to the prompt allowance of this Application remain that is susceptible to being clarified by a telephonic interview or overcome by an examiner's amendment.

DATED this 13th day of April, 2009

Respectfully submitted,

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